

REMARKS

Reconsideration and allowance of the application are respectfully requested in light of the foregoing amendments and the following remarks.

Claims 45-86 are pending in the application. Claims 85-86 have been withdrawn from consideration. Independent Claim 45 is herein amended to describe the pre-determined relative ratio of the lipid blend to the non-aqueous solvent as being “of from about 5 mg of lipid blend per mL of non-aqueous solvent to about 15 mg/mL.” Support for this amendment may be found in the specification on page 4, lines 35 – 37.

Entry of the foregoing amendment is respectfully requested.

Claims 45, 48, 50 and 52 were again rejected under 35 U.S.C. §102(e) for alleged anticipation in view of Nyberg et al., U.S. Patent No. 5,677,472. This rejection is respectfully traversed for the following reasons.

In order for a rejection under Section 102 to be proper, each and every element of the claim must be found in the cited art reference. Nyberg et al. in Example 1 starts with a relative weight ratio of the lipids PE and PC, and sphingomyelin of 14 : 14 : 10, or 1.4 : 1.4 : 1, respectively. After the first precipitation, the composition then contains 3% each of PE and PC, and 60% sphingomyelin. This results in a ratio of 1 : 1 : 20. In other words, Nyberg et al. clearly does not disclose the present limitation in which “the relative ratio of phospholipids in said solid phospholipid blend [after precipitation] corresponds to said predetermined relative ratio in the non-aqueous solution of step (a).” Stated another way, Nyberg et al. discloses far greater relative amounts of sphingomyelin than either PE or PC, after precipitation, than was contained in the starting solution. This is in direct contrast to what the present applicants have claimed.

Since Nyberg et al. does not recite each and other feature of the presently claimed invention, then this reference can not anticipate the present claims. Withdrawal of the §102(e) rejection is therefore respectfully urged.

Claims 45 and 47-84 were rejected under 35 U.S.C. §103(a) for alleged obviousness over Nyberg et al. above, in view of Fischer et al. (U.S. Patent No. 5,840,661), Unger et al. (U.S. Patent No. 5,585,112), Unger et al. (U.S. Patent No. 6,416,740) and Senior et al. (Biochimica et Biophysica Acta, 1991, 1062, pp. 77-82). This rejection is also respectfully traversed for the following reasons.

The shortcomings of Nyberg et al. are discussed above. This reference fails to teach or even suggest how to precipitate a solid blend of phospholipids in which the relative ratio of the lipids corresponds to that contained in the starting solution. This important defect is not remedied by any of the four cited secondary references of Fisher et al., Unger et al. or the journal article, either alone or in combination. For example, Fischer et al.’s discussion of solvent equivalence fails to address the core issue of preserving the

phospholipids in the final precipitate. Similarly, both Unger et al.'s discussions of making and/or sterilizing a phospholipid also begs the primary issue. Finally, Senior et al.'s discussion regarding DPPE-PEG 5000 would not have aided the skilled artisan in overcoming the primary teachings of Nyberg et al. to separate as much of one phospholipid from a group of lipids.

Based on the foregoing, it is respectfully submitted that the combination of Nyberg et al. and the cited secondary references does not render obvious the presently claimed invention. For these reasons, it is further respectfully urged that the §103 (a) rejections be withdrawn.

Finally, claims 45 and 47-52 were rejected under 35 U.S.C. §103(a) for alleged obviousness over Unger et al. (U.S. Patent No. 6,521,211). This rejection is also respectfully traversed. There does not appear to be any suggestion in the Unger '211 reference to utilize a relative ratio of lipids to solvent in step (a) of about 5:1 to 15:1. For at least this reason, Unger et al. does not render obvious the claimed invention. Withdrawal of the §103(a) rejection is therefore respectfully requested.

The application is believed to be in proper condition for allowance, and prompt, favorable action thereon is earnestly solicited. Should Examiner Huynh feel that any other point requires consideration, then he is cordially invited to contact the undersigned.

Respectfully submitted,

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